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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,782	04/02/2004	Steven Griffiths	VA/H-32318B	3493
1095	7590	01/24/2006	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,782

Applicant(s)

GRIFFITHS ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213:

Disposition of Claims

- 4) ☒ Claim(s) 38-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/049,086.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Sequence Alignment.

DETAILED ACTION

1. Applicant's preliminary amendment filed December 12, 2003 is acknowledged and entered. Claims 38-42 are pending and under examination.

Amendment to Correct Inventorship 37 C.F.R. 1.48(a)

2. In view of the papers filed January 18, 2005, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding the name Joel Heppell as one of the co-inventors.

Specification

3. The specification is objected to because of the following:
 - ❖ The sequences in the drawings must be referenced by sequence identifiers. (SEQ ID NO:)
 - ❖ The first line of the first page of the specification fails to reflect the updated status of parent application USSN 10/049,086, now US Patent 6,919,083.
 - ❖ Figures 7 and 8 are not referenced in the specification.

Correction is required to overcome these objections to the specification.

Priority

4. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Certified copies of 9918588.6 and 0005848.7 have been filed in parent

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Application No. 10/049,086, filed on February 6, 2002. It is noted, however, that Applicant has not filed a certified copy of the 0006674.6 application as required by 35 U.S.C. 119(b). The examiner notes that this document has been previously indicated as present in the parent application. However, a copy of the document cannot be located in the parent application. Applicant is requested to file a copy of the document. The Office regrets any inconvenience.

Claim Rejections - 35 USC § 112

5 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to an isolated protein comprising an amino acid sequence according to SEQ ID NO: 4 or a derivative thereof, wherein the derivative thereof has antigenic or immunogenic characteristics of the amino acid sequence according to SEQ ID NO: 4. Also claimed are kits, vaccines and pharmaceutical compositions comprising the claimed peptide.

The metes and bounds of the claimed peptide derivative cannot be determined without a clear definition of the derivative. While Applicant has provided a functional definition of the claimed peptide, the structural definition is lacking. It is unclear what portions of SEQ ID NO: 4 are retained in the derivative so that it remains immunogenic. Further, it is unclear what antigenic or immunogenic characteristics of the derived peptide must be shared with SEQ ID NO: 4. It is suggested that references to derivatives be deleted from the claims in order to overcome this rejection.


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Conclusion

6. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. With regard to SEQ ID NO: 4, US Patent 6,471,964 B1, discloses and claims a sequence having 97.4% sequence identity to SEQ ID NO: 4 (see attached Sequence Alignment). Because the priority date granted to the patent (October 18, 1999) is later than the earliest priority date of the instant application (August 8, 1999), the patent is not available as prior art, although the derivatives instantly claimed are encompassed by the disclosure and claims of the patent.

No claim is allowed. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
January 18, 2006

Sequence Alignment

GenCore version 5.1.6
Copyright (c) 1993 - 2006 Compugen Ltd.

OM protein - protein search, using sw model

Run on: January 13, 2006, 09:27:05 ; Search time 27 Seconds
(without alignments)
1886.230 Million cell updates/sec

Title: US-10-734-782-4
Perfect score: 3097
Sequence: 1 MADKGMTYSFVDVRLNTLVVR.....DWTPEIFDEDEBEREDIDI 616

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 572060 seqs, 82675679 residues
Total number of hits satisfying chosen parameters: 572060

Minimum DB seq length: 0
Maximum DB seq length: 2000000000
Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

- Database : Issued Patents AA:*
- 1: /cgn2_6/ptodata/1/iaa/5 COMB.pcp.*
 - 2: /cgn2_6/ptodata/1/iaa/6 COMB.pcp.*
 - 3: /cgn2_6/ptodata/1/iaa/7 COMB.pcp.*
 - 4: /cgn2_6/ptodata/1/iaa/8 COMB.pcp.*
 - 5: /cgn2_6/ptodata/1/iaa/9 COMB.pcp.*
 - 6: /cgn2_6/ptodata/1/iaa/backfiles1.pcp.*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	DB ID	Description
1	3097	100.0	616	2	US-10-049-086-4
2	3015	97.4	616	2	US-09-690-185A-2
3	128	4.1	1095	2	US-09-206-942-45
4	128	4.1	1101	2	US-09-206-942-43
5	118	3.8	584	2	US-09-107-532A-6970
6	116.5	3.8	2042	2	US-09-077-098A-6
7	116.5	3.8	2042	2	US-10-192-584-6
8	116	3.7	1166	2	US-09-200-6508-7
9	116	3.7	1781	1	US-08-477-451-11
10	115	3.7	1085	2	US-09-206-942-69
11	115	3.7	1095	2	US-10-193-764-65
12	115	3.7	1536	1	US-08-038-682-2
13	115	3.7	1536	1	US-08-302-832-2
14	115	3.7	1536	1	US-08-530-198-2
15	115	3.7	1536	1	US-08-469-980-2
16	115	3.7	1536	1	US-08-728-470-2
17	115	3.7	1536	1	US-08-617-697-2
18	115	3.7	1536	2	US-08-719-641-2
19	115	3.7	1536	2	US-09-206-942-67
20	115	3.7	1536	2	US-10-193-764-63
21	114	3.7	2048	2	US-09-268-347-48
22	114	3.7	3241	2	US-09-841-786-1
23	113	3.6	504	2	US-09-949-016-7935
24	112.5	3.6	1572	2	US-09-710-279-2906
25	112.5	3.6	4536	2	US-09-180-422B-27
26	112.5	3.6	4536	2	US-09-079-030-1
27	112.5	3.6	4563	2	US-09-108-006C-1

ALIGNMENTS

RESULT 1

US-10-049-086-4
; Sequence 4, Application US/10049086
; Patent No. 6919083

GENERAL INFORMATION:
; APPLICANT: Aqua Health (Europe) Limited
; APPLICANT: Griffiths, Steven
; APPLICANT: Ritchie, Rachael
; TITLE OF INVENTION: Sequence
; FILE REFERENCE: P24268-/GST/RMC
; CURRENT APPLICATION NUMBER: US/10/049,086
; PRIOR FILING DATE: 2002-02-06
; PRIOR APPLICATION NUMBER: GB9918588.6
; PRIOR FILING DATE: 1999-07-08
; PRIOR APPLICATION NUMBER: GB0005848.7
; PRIOR FILING DATE: 2000-03-11
; PRIOR APPLICATION NUMBER: GB0006674.6
; PRIOR FILING DATE: 2000-03-21
; NUMBER OF SEQ ID NOS: 10
; SOFTWARE: Patent in version 3.0
; SEQ ID NO 4
; LENGTH: 616

TYPE: PRT
; ORGANISM: Salmon Anaemia Virus
US-10-049-086-4

Query Match 100.0%; Score 3097; DB 2; Length 616;
Best Local Similarity 100.0%; Pred. No. 3.7e-309;
Matches 616; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY	1	MADKGMTYSFVDVRLNTLVVRSTATSGIKISYREDRGTSLLQKAFAGTEDEFWELDDQD	60
DB	1	MADKGMTYSFVDVRLNTLVVRSTATSGIKISYREDRGTSLLQKAFAGTEDEFWELDDQD	60
QY	61	VYDKKIRKFLBEERKMKOMSTRVSGAVAAAIERSVEFDNFPSKEAAANIENAGVDDREAGG	120
DB	61	VYDKKIRKFLBEERKMKOMSTRVSGAVAAAIERSVEFDNFPSKEAAANIENAGVDDREAGG	120
QY	121	SGLVNRRKNGKVSNNAYNLSPFGMVFPALTFPSAILSEGMSIWQNGQAILRIALALA	180
DB	121	SGLVNRRKNGKVSNNAYNLSPFGMVFPALTFPSAILSEGMSIWQNGQAILRIALALA	180
QY	181	DEDEGKQRTTGQORVDMADVTKLVVVTANGKVKQVEVNLNDLKAAFQSRPKESDYRKQ	240
DB	181	DEDEGKQRTTGQORVDMADVTKLVVVTANGKVKQVEVNLNDLKAAFQSRPKESDYRKQ	240
QY	241	GSKATSESSINOCMALIMKSVLSADQLFAPGVOMRTNGFNASYTTLAGANIPSKYLRLH	300
DB	241	GSKATSESSINOCMALIMKSVLSADQLFAPGVOMRTNGFNASYTTLAGANIPSKYLRLH	300

301 MRNCGVALDLMGMRIRKNSPEGAKSKIFSIIOKKVGRGCRTEORLLTSALKISDGENK 360
 301 MRNCGVALDLMGMRIRKNSPEGAKSKIFSIIOKKVGRGCRTEORLLTSALKISDGENK 360
 361 FORIMDTLCTSLFDIPPRTKCFIPPISSLMYIOEGNSVLAMDFWNGEDACKICREAK 420
 361 FORIMDTLCTSLFDIPPRTKCFIPPISSLMYIOEGNSVLAMDFWNGEDACKICREAK 420
 421 LKGVNSTFTMSVARTCVAVSMVATAPCSADIIENAVPGSERYRSNIKANTTKPKKOSTY 480
 421 LKGVNSTFTMSVARTCVAVSMVATAPCSADIIENAVPGSERYRSNIKANTTKPKKOSTY 480
 481 TIQGLRLSNVRYEAPETQSNTDRSQWNVNTPDSFGLAVFNQGAIREMLGDTSETTSV 540
 481 TIQGLRLSNVRYEAPETQSNTDRSQWNVNTPDSFGLAVFNQGAIREMLGDTSETTSV 540
 541 NVRALVKRILKSASERSARAVKTFMVGQKSAIVISGVGLFSIDPEGVEAERITDMTP 600
 541 NVRALVKRILKSASERSARAVKTFMVGQKSAIVISGVGLFSIDPEGVEAERITDMTP 600
 601 EIEFDEDDDEEEDIDI 616
 601 EIEFDEDDDEEEDIDI 616

RESULT 2

US-09-690-185A-2
 ; Sequence 2, Application US/09690185A
 ; Patent No. 6471964
 ; GENERAL INFORMATION:
 ; APPLICANT: KROSSOY, BJORN
 ; APPLICANT: BIERING, BIRIK
 ; TITLE OF INVENTION: DNA ENCODING STRUCTURAL PROTEIN-1 OF INFECTIOUS SALMON
 ; TITLE OF INVENTION: ANAEMIA VIRUS AND USES THEREOF
 ; FILE REFERENCE: BIERING
 ; CURRENT APPLICATION NUMBER: US/09/690,185A
 ; CURRENT FILING DATE: 2000-10-17
 ; PRIOR APPLICATION NUMBER: EP99203401.7
 ; PRIOR FILING DATE: 1999-10-18
 ; NUMBER OF SEQ ID NOS: 8
 ; SOFTWARE: PatentIn Ver. 2.1
 ; SEQ ID NO 2
 ; LENGTH: 616
 ; TYPE: PRP
 ; ORGANISM: Infectious salmon anemia virus
 ; ORGANISM: Infectious salmon anemia virus
 ; US-09-690-185A-2

Query Match 97.4%; Score 3015; DB 2; Length 616;

Best Local Similarity 96.3%; Pred. No. 1e-300;

Matches 593; Conservative 17; Mismatches 6; Indels 0; Gaps 0;

QY 1 MADKGMTYSPDVRDNTLVRRSTATSGIKISYREDRGTSLLQKAPAGTDEDFWVLDQD 60
 DB 1 MADKGMTYSPDVRDNTLVRRSTATSGIKISYREDRGTSLLQKAPAGTDEDFWVLDQD 60
 QY 61 VYDVKIRFLFEKKKMDSTRVSGVAAAIERSVEFDNFSKEAANAIEAGVDDREAGG 120
 DB 61 VYDVKIRFLFEKKKMDSPRCSGVAAAIERSVEFDNFSKEAANAIEAGVDDREAGG 120
 QY 121 SGLVDRNRKKGVSNNAYNLSLPIGMVFPALTTFFSAILSEGEWSIWONGQAIIRILALA 180
 DB 121 SGLVDRNRKKGVSNNAYNLSLPIGMVFPALTTFFSAILSEGEWSIWONGQAIIRILALA 180
 QY 181 DEBKGRTTGGORVDMADVTKLVNTVANGKQVENVNLDLKAAPRQSRPRKSDYRKQ 240
 DB 181 DEBKGRTTGGORVDMADVTKLVNTVANGKQVENVNLDLKAAPRQSRPRKSDYRKQ 240
 QY 241 GSKATSESSINOCMALIMKSVLSADQLFAPGVQMTNGFNASYTTLAGANIPSKYLH 300
 DB 241 GSKATSESSINOCMALIMKSVLSADQLFAPGVQMTNGFNASYTTLAGANIPSKYLH 300
 301 MRNCGVALDLMGMRIRKNSPEGAKSKIFSIIOKKVGRGCRTEORLLTSALKISDGENK 360

Jan 13 11:33:02 2006

Db 301 MRNCGVALDLMGMRIRKNSPEGAKSKIFSIIOKKVGRGCRTEORLLTSALKISDGENK 360
 QY 361 FORIMDTLCTSLFDIPPRTKCFIPPISSLMYIOEGNSVLAMDFWNGEDACKICREAK 420
 Db 361 FORIMDTLCTSLFDIPPRTKCFIPPISSLMYIOEGNSVLAMDFWNGEDACKICREAK 420
 QY 421 LKGVNSTFTMSVARTCVAVSMVATAPCSADIIENAVPGSERYRSNIKANTTKPKKOSTY 480
 Db 421 LKGVNSTFTMSVARTCVAVSMVATAPCSADIIENAVPGSERYRSNIKANTTKPKKOSTY 480
 QY 481 TIQGLRLSNVRYEAPETQSNTDRSQWNVNTPDSFGLAVFNQGAIREMLGDTSETTSV 540
 Db 481 TIQGLRLSNVRYEAPETQSNTDRSQWNVNTPDSFGLAVFNQGAIREMLGDTSETTSV 540
 QY 541 NVRALVKRILKSASERSARAVKTFMVGQKSAIVISGVGLFSIDPEGVEAERITDMTP 600
 Db 541 NVRALVKRILKSASERSARAVKTFMVGQKSAIVISGVGLFSIDPEGVEAERITDMTP 600
 QY 601 EIEFDEDDDEEEDIDI 616
 Db 601 EIEFDEDDDEEEDIDI 616

RESULT 3

US-09-206-942-45
 ; Sequence 45, Application US/09206942
 ; Patent No. 6432269
 ; GENERAL INFORMATION:
 ; APPLICANT: Loomore, Sheena M.
 ; APPLICANT: Yang, Yan-Ping
 ; APPLICANT: Klein, Michel H.
 ; TITLE OF INVENTION: Protective Recombinant Haemophilus Influenzae High
 ; TITLE OF INVENTION: Molecular Weight Proteins
 ; FILE REFERENCE: 1038-861 MIS:1b
 ; CURRENT APPLICATION NUMBER: US/09/206,942
 ; CURRENT FILING DATE: 1998-12-08
 ; EARLIER APPLICATION NUMBER: 09/167,568
 ; EARLIER FILING DATE: 1998-10-07
 ; NUMBER OF SEQ ID NOS: 95
 ; SOFTWARE: PatentIn Ver. 2.1
 ; SEQ ID NO 45
 ; LENGTH: 1095
 ; TYPE: PRP
 ; ORGANISM: Haemophilus influenzae
 ; ORGANISM: Haemophilus influenzae
 ; US-09-206-942-45

Query Match 4.1%; Score 128; DB 2; Length 1095;

Best Local Similarity 19.1%; Pred. No. 0.0023;

Matches 121; Conservative 73; Mismatches 264; Indels 176; Gaps 23;

QY 32 SYREDRGTSLLQKAPAGTDEDFWVE-----LDQDVYVDKIRKFLBEKKMD 78
 DB 332 NFNAEGSLRPFKSGSTRFTATIESDTILNATGNSILNQVAGIDGMLQKSLVAN--KN 389
 QY 79 MSTRVSGVAAAIERSVEFDNFSKEAANAIEAGVDDREAGG 133
 DB 390 ITFEGGNTTAAOKKPIBKGNITVKEGANVTIRSGANTGNDKSALSIRGNVTN-KGNLTV 448
 QY 134 SNMAYNLSLPIGMVFPALTTFFSAILSEGEWSIWONGQAIIRILALADBDGRQ---TFT 190
 DB 449 TGSALNIE-----KNLTVESAKFLANPNYSFNVSGLFDNQGKSNISIAKG 494
 QY 191 GSGRVDMADVTKLVNTV-----ANGVK-----QVENVNLDLKA 224
 DB 495 GAHFKDINTKSLNTTNSDSAYRTIIEGNTNSGDLNITNKNNAEIQIGNISQKEG 554
 QY 225 AFRQSRPK-----RSDYRKGGKSKATSESSINOCMALIMKSVLSADQLFAPGVQMTNG 279
 DB 555 NLTISSDKINITNQITIKKGVNKEDSDSTANNANLTIKTKE-----QLTGD---LNISG 607
 QY 280 FNASTYTTLAGANIPSKYLHNRWNGCGVALDLMGMRIRKNSPEGAKSKIFSIIOKKVGR 339
 DB 608 FDKABITAKEGADL-----IIGNSDNNNNANAKKVTNPNQVQKDSKISA- 649